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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,958	08/13/2001	Masayoshi Nanba	2519US0P	8993
23115	7590	02/28/2006	EXAMINER	
TAKEDA PHARMACEUTICALS NORTH AMERICA, INC INTELLECTUAL PROPERTY DEPARTMENT 475 HALF DAY ROAD SUITE 500 LINCOLNSHIRE, IL 60069			WHITEMAN, BRIAN A	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 02/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/673,958	NANBA ET AL.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5 is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### **Non-Final Rejection**

Claims 1, 2, and 5 are pending.

Applicant's traversal and the amendment to claim 5 in paper filed on 1/11/06 is acknowledged and considered by the examiner.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Blasser et al. (WO 98/08935, cited on a PTO-1449). Blasser teaches an immortalized hepatic cell line abstract. The immortalized cell line taught by Blasser meets the structural limitations of the claim and the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). See also In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977) and In re Fitzgerald, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980).

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Claims 1 and 2 remain rejected under 35 U.S.C. 102(b) as being anticipated by Pfeifer et al. (PNAS, Vol. 90, pages 5123-5127, cited on a previous PTO-892).

Instant claim 1 reads on an immortalized hepatocyte cell culture of human normal cell origin which can be induced to express genes encoding enzymes involved in the metabolism of xenobiotics in the liver, wherein said enzymes are CYP1A1, CYP1A2, and CYP3A. In view of the term "induced to express genes", the cell line is not required to express said enzymes but only required to be able to express the genes when exposed to an agent that would induce expression of the genes. In addition, the cell line reads on a cell line that could be genetically modified by inserting an exogenous gene comprising the enzymes operably linked to an inducible promoter into the cells.

Pfeifer anticipates the immortalized hepatocyte cell culture in claim 1. Pfeifer teaches immortalized human liver cell culture that expresses hepatocyte characteristics (abstract). The liver cell culture taught by Pfeifer expresses CYP1A1/1A2, epoxide hydrolase, NADPH CYP reductase, SOD, catalase, glutathione S-transferase, and glutathione peroxidase (pages 5126-5127). It is acknowledged that Pfeifer does not specifically teach the cell culture comprising all three enzymes. However, the immortalized cell line taught by Pfeifer meets the structural limitations of the claim and the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). See also *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980).

Furthermore, Pfeifer anticipates claim 2 because Pfeifer teaches that the immortalized human liver cell culture further retains NADPH CYP reductase (NADPH cytochrome P450 reductase) (pages 5126-5127).

Applicant's arguments filed 1/11/06 have been fully considered but they are not found persuasive.

In response to applicant's argument that the cell line of Pfeifer does not express CYP1A2, the argument is not found persuasive because the alternative language of the claim embraces a cell line that would be capable to express the gene products when exposed to an agent that would induce expression of the genes or inserting an exogenous gene comprising the enzymes operably linked to an inducible promoter into the cells.

In response to applicant's argument that the cell line of Pfeifer does not express CYP3A as admitted by the office and the citation of *Atlas Powder Co. v. Ireco, Inc.* is improperly applied to the present case as there is no reasonable belief that the teaching of prior art meets the structural limitation of the claimed invention, the argument is not found persuasive because the alternative language of the claim embraces a cell line that would be capable to express the gene products when exposed to an agent that would induce expression of the genes or inserting an exogenous gene comprising the enzymes operably linked to an inducible promoter into the cells. Furthermore, the cell line taught by Pfeifer is a human immortalized hepatocyte cell line, which is the same cell line as required in the instant claims.

*Conclusion*

Claim 5 is in condition for allowance because the claim is free of the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, acting SPE – Art Unit 1635, can be reached at (571) 272-0811.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman  
Patent Examiner, Group 1635

